



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-N-0008]

### Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will take place virtually on August 22 and 23, 2023, from 9 a.m. to 6 p.m. Eastern Time.

**ADDRESSES:** All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions, including information regarding special accommodations due to a disability, may be accessed at:

<https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

**FOR FURTHER INFORMATION CONTACT:** Jarrod Collier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993-0002, [Jarrod.Collier@fda.hhs.gov](mailto:Jarrod.Collier@fda.hhs.gov), 240-672-5763, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the *Federal Register* about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide

timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

#### **SUPPLEMENTARY INFORMATION:**

*Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On both days, the committee will discuss, make recommendations, and vote on devices indicated to reduce blood pressure in patients with hypertension. On August 22, 2023, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the ReCor Paradise Ultrasound Renal Denervation System by ReCor, Inc. The proposed indication for use statement is as follows: The ReCor Paradise Ultrasound Renal Denervation System is indicated to reduce blood pressure in adult ( $\geq 22$  years of age) patients with uncontrolled hypertension, who may be inadequately responsive to, or who are intolerant to, antihypertensive medications, which is intended to be used in renal arteries of diameters ranging from 3.0 to 8.0 mm.

On August 23, 2023, the committee will discuss, make recommendations, and vote on information regarding the PMA for the Medtronic Symplicity Spyral Renal Denervation System by Medtronic, Inc. The proposed indication for use statement is as follows: The Symplicity Spyral multielectrode renal denervation catheter and the Symplicity G3 RF Generator are indicated for the reduction of blood pressure in patients with uncontrolled hypertension despite the use of antihypertensive medications or in patients in whom blood pressure lowering therapy is poorly tolerated.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's

website after the meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down and select the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 1, 2023. Oral presentations from the public will be scheduled on August 22 and 23, 2023 between approximately 1:30 p.m. and 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see FOR FURTHER INFORMATION CONTACT) and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 24, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 25, 2023.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Ann Marie Williams at [Annmarie.williams@fda.hhs.gov](mailto:Annmarie.williams@fda.hhs.gov) or 240-507-6496 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 14, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023-13136 Filed: 6/20/2023 8:45 am; Publication Date: 6/21/2023]